# Mayo Clinic gets FDA approval for new imaging agent for recurrent prostate cancer

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Mayo Clinic has received U.S. Food and Drug Administration approval to produce and administer Choline C 11 Injection, an imaging agent used during a positron emission tomography (PET) scan to help detect sites of recurrent prostate cancer. Mayo Clinic is the first, and currently only, institution in North America approved to produce this imaging agent.

Choline C 11 Injection is a radioactive form of the vitamin choline. Clinicians inject a small amount of the agent into a patient's vein and then use a PET scanner and computer to make detailed pictures of areas where the agent collects. Since cancer cells take up more Choline C 11 than do normal cells, the pictures can be used to help find areas of possible cancer in the body when bone scintigraphy, computerized tomography or magnetic resonance imaging is non-informative. Once a site is identified, a biopsy and pathologic examination can verify whether prostate cancer has recurred.

Evaluating men for prostate cancer recurrence has long been a major challenge; physicians have had to wait until a patient's prostate-specific antigen (PSA) levels rose to values between 20-30 ng/mL to identify sites of recurrent prostate cancer.

"This technology is a game changer," says Eugene Kwon, M.D., a urologist at Mayo Clinic. "In stark contrast to conventional imaging, PET imaging with Choline C 11 Injection can help identify sites of recurrence for tissue sampling and examination when a patient's PSA level reaches

2 ng/mL—months or even years earlier than before. This technology also allows us to pinpoint the locations of recurrent cancer more accurately and permits us to develop more effective treatment strategies."

About 90,000 men annually seek treatment for recurrent prostate cancer, according to the Surveillance, Epidemiology and End Results database. Recurrent prostate cancer is defined as cancer that has recurred following initial therapy, which could include surgery, radiation therapy, hormone therapy or chemotherapy.

Choline C 11 Injection has a short shelf life and must be made in a specialized facility and given to patients within minutes after production. Mayo Clinic has the integrated production, imaging and pathology facilities to provide the benefit of Choline C 11 PET imaging to patients.

Choline C 11 Injection is a perfect fit for Mayo because its urologists see some of the most complex cases of recurrent prostate cancer in the country, Dr. Kwon says. He cautions that even with its advantage over conventional imaging, PET imaging with Choline C 11 injection is not a replacement for a tissue biopsy and histologic verification of recurrent prostate cancer.

"We worked very closely with the FDA to obtain approval to administer this agent," says Val Lowe, M.D., a radiologist at Mayo Clinic who worked on the new drug application. "The FDA understood our needs as an academic institution trying to bring novel technology to the clinician and they were very responsive."

The safety and effectiveness of Choline C 11 Injection were verified by a systematic review of published study reports.

Possible allergic reactions and mild injection site reactions may occur with the use of Choline C 11 Injection. However, no adverse reactions to

Choline C 11 Injection have been reported other than a mild injection site reaction. Choline C 11 Injection contributes to a patient's long-term cumulative radiation exposure. Imaging errors have been reported; in particular, blood PSA levels

Provided by Mayo Clinic